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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,757	02/12/2001	Robert W. Mahley	6510096CIP3	9705

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,757	MAHLEY ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-18 and 23-28* is/are pending in the application.

4a) Of the above claim(s) *5-18 and 23-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/13/06*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 20, 2005 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed July 20, 2005, and amendment and response to the Office Action (mailed August 25, 2004), filed July 20, 2005 wherein claims 2, 4, 19-22, and 29 are cancelled; claims 1 and 3 have been amended.

Currently, claims 1, 3, 5-18, and 23-28 are pending in this application.

It is noted that Claims 5-18 and 23-28 are withdrawn from further consideration pursuant to 37 CFR 1 .142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse on September 11, 2002, recorded in the previous Office Action December 18, 2002.

Claims 1 and 3 are examined on the merits herein.

Priority

This application is a continuation in part of 09/070675 which is a continuation in part of 08/659785 which Claims Priority from Provisional Application 60/005550 filed 10/17/1995.

However, the parent applications, upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the instant claims 1 and 3 as amended now, reciting "a disulfonate wherein said disulfonate binds specifically to apolipoprotein E4 (apoE4) and disrupts domain interaction within the apoEx protein, thereby reducing domain interaction by at least about 10%".Thus, the filing date of the instant claims is deemed to be the filing date of the instant filing date, February 12, 2001. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

In clarifying the priority date of the instant claims, applicant should note or address whether the art rejections are prior to the priority date of the instant claims and whether said art occurred more than one year prior to said priority date. Applicant will note that the art rejections are under both 35 U.S.C. § 102(a) and 102(b) because the priority date of the instant claims is in question.

The following is new rejection(s) necessitated by Applicant's amendment filed on July 20, 2005, wherein claims 2, 4, 19-22, and 29 are cancelled and the limitations in the amended claims 1 and 3 have been changed.

Therefore, all rejections of record in the previous Office Action August 25, 2004 are withdrawn, in favor of the new rejections below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **full** possession of the claimed invention.

The claims herein are drawn to the use of any agents represented by "a disulfonate wherein said disulfonate binds specifically to apolipoprotein E4 (apoE4) and disrupts domain interaction within the apoEx protein, thereby reducing domain interaction by at least about 10%". Thus, the recitation in the claims are deemed to a broad genus of any compounds represented by "disulfonate" having the recited function.

The specification as originally filed does not provide adequate support for a generic claims herein. The specification merely describes a **single** specific compound, "Azocarmine G" also known as "Benzo[a]phenazinium, 7-phenylsulfo-5-[(4-sulfophenyl)amino]-, hydroxide,inner salt, monosodium salt", (see page 15 line 1 and Table 9 at page 67). The specification has not taught any other disulfonates are intended to be encompassed within the scope of claims. According to CAS STN Registry, there are "**3277**" compounds having disulfonate moiety, for example, "Aniline, N-methyl-, 2,7-naphthalenedisulfonate", 2-"Naphthylamine, 5,6,7,8-tetrahydro-, methanedisulfonate", "Aniline, m-bromo-, 2,6-naphthalenedisulfonate", "Aniline, 1,2-

ethanedisulfonate" (see their names and structures provided by STN Registry, PTO-892). Thus, the broad genus of any compounds represented by "disulfonate" would reasonably encompass all 3277 known disulfonate compounds including these example compounds.

More importantly, one of ordinary skill in the art would clearly recognize that the structure of Azocarmine G differs by a significant structural feature from those specific examples, disulfonate compounds above, provided by STN.

Given the fact that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical, chemical, physiological effects and functions. Thus, the activity and properties of Azocarmine G would be reasonably expected to separate and distinct from "Aniline, N-methyl-, 2,7-naphthalenedisulfonate", 2-"Naphthylamine, 5,6,7,8-tetrahydro-, methanedisulfonate", "Aniline, m-bromo-, 2,6-naphthalenedisulfonate", "Aniline, 1,2-ethanedisulfonate".

The court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability .....of any other species." (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, an no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

In this case, the claimed disulfonate herein is deemed not to adequately described in the sepecifcaton. Thus, ordinary artisans could not predict the operability of all other disulfonate compounds, except for Azocarmine G. Thus, the claimed composition is seen to clearly lack of written description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Pravabati et al. ("Azocarmine induced hematological and biochemical changes in albino rat, Rattus norvegicus L", PTO-892).

Pravabati et al. discloses a composition comprising an effective amount or dose of Azocarmine G injected i.p. on every 3rd day in the blood of rats after 30, 60, and 90 days. Note that Azocarmine G in the injectable aqueous solution. Hence water is a known pharmaceutical acceptable excipient. See abstract in particular.

Further, note that it is well settled that "intended use" of a composition or product, e.g., a disulfonate "wherein said disulfonate binds specifically to apolipoprotein E4 (apoE4) and disrupts domain interaction within the apoEx protein, thereby reducing domain interaction by at least about 10%", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition

comprising the same ingredients as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, the disclosure of Pravabati et al. anticipates claims 1 and 3.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Murakami et al. ("Dark and light neurons in the human brain, with special reference to their reactions to Golgi's silver nitrate, Luxol Fast Blue MBS and azocarmine G", PTO-892).

Murakami et al. discloses a composition comprising azocarmine G in an aqueous solution. Hence water is a known pharmaceutical acceptable excipient. See abstract in particular.

As indicated above, "intended use" of a composition or product, e.g., a disulfonate "wherein said disulfonate binds specifically to apolipoprotein E4 (apoE4) and disrupts domain interaction within the apoEx protein, thereby reducing domain interaction by at least about 10%", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, the disclosure of Murakami et al. anticipates claims 1 and 3.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al. ("Cytofluorometric nuclear DNA determinations on the atrioventricular nodal cells in human hearts", PTO-892).

Hayashi et al. discloses a composition comprising azocarmine G in an aqueous solution with human heart cells. Hence water is a known pharmaceutical acceptable excipient. See abstract in particular.

As indicated above, "intended use" of a composition or product, e.g., a disulfonate "wherein said disulfonate binds specifically to apolipoprotein E4 (apoE4) and disrupts domain interaction within the apoEx protein, thereby reducing domain interaction by at least about 10%", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, the disclosure of Hayashi et al. anticipates claims 1 and 3.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
September 8, 2005